

A Prospective Observational Study to Assess Prescription Pattern for Various Hepatic Dysfunctions in a Tertiary Care Teaching Hospital

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Abstract:

BACKGROUND:- The purpose of the study was to assess the prescription pattern for various hepatic dysfunctions in liver disorders.

Methodology: This is a prospective observational study carried out on 160 patients at the Department of General Medicine, Vijayanagara Institute of Medical Sciences from October 2018 to March 2019. All inpatients including male and female diagnosed with liver dysfunction were included in the study. Demographic data, clinical course and outcome were analysed.

Results: The major cause of liver disease was found to be alcohol consumption(123patients). WHO prescribing indicators showed deviation from standard reference values. Most of the prescriptions were irrational because no dose tapering has been done in the patient prescription.

Conclusion:- Drug utilization and evaluation will bring a change in the prescribing patterns. Increasing the involvement of clinical pharmacist and physicians in clinical rounds by promoting rational drug use and drug adherence may improve the quality of health of patients.

Keywords:- Prescription pattern, Drug utilization, dose tapering, irrational prescription, portal hypertension.

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I. Introduction

The liver is the most metabolically complex organ with hepatocytes¹. It performs multiple functions such as protein synthesis, secretion of enzymes, detoxification of drugs and other foreign substances, metabolism of fats, carbohydrates and blood clotting factors¹. Liver failure (LF) is divided into two categories: Acute LF and Chronic LF. Alcohol and drug abuse are the major causes of LF and viral infection are predominant cause². Mainly liver disease is caused by viral infections, alcoholic, non-alcoholic, immune disorders, vascular abnormalities, metabolic and genetic disorders, drug induced like acetaminophen and idiosyncratic drugs¹. ALD comprise of 3 main types: fatty liver, liver cirrhosis and alcoholic hepatitis⁴. Alcoholic liver disease (ALD) is a serious disorder due to excessive alcohol consumption. Excess alcohol ingestion is the leading cause of death in people age group between 15-49 years⁴. The factors that affect and progress the alcoholic liver injury including dose and frequency of alcohol consumption, sex ethnicity, and associated risk factors such as obesity, viral disease and genetic factors. The histological spectrum of ALD may differ from simple fatty liver to cirrhosis inclusive of hepatocellular carcinoma. If treatment starts on time, ALD is preventable and reversible⁵.

Non-alcoholic fatty liver disease (NAFLD) is a common condition characterized by excess of fat in liver. NAFLD is a major public health problem due to obesity and type 2 diabetes⁷. It is most frequently recognized in men and postmenopausal women who not received hormone replacement therapy (HRT)⁸. DILI is common cause of ALF in Western world; with acetaminophen being the commonest drug followed by antimicrobials where as in India anti tubercular drugs are more common cause of drug induced⁹. Acetaminophen is a hepatotoxicity drug at higher dose, but it can be used safely in maximum daily dose 2-3 grams per day or up to 4 grams per day¹⁰. Drugs other than acetaminophen rarely cause dose related toxicity most E.g. idiosyncratic

drugs hepatotoxicity occurs within the first 6 month after drug consumption. Hepatotoxicity drugs that has been used continually more than 1 to 2 years is unlikely to cause de nova liver damage³.

Traditional medical prescription and herbal remedies may also cause hepatotoxicity¹³. Medicines are the primary part of the health care, without the availability of necessary medicines modern health care is not viable. They not only safe lives and promote health, but prevent epidemics diseases also. Accessibility to medicines is the fundamental right of every person. However, to bring optimal benefit, they should be safe, efficacious, cost-effective and rational¹⁴. Prescription Pattern Monitoring Studies (PPMS) are drug utilization studies which focus mainly on prescribing, dispensing, administering and taking of medicines. They support proper use of monitored drugs and reduction of abuse or misuse of monitored drugs. PPMS also guide and support prescribers, dispensers and the general public on proper use of drugs, collaborate and develop working relationship with other key organizations to achieve a rational use of drugs¹⁴. The main aim of PPMS is to assist the rational use of drugs in a population¹⁴. Rational drug prescribing can be defined as appropriate drugs prescribed in the right dose, at correct time intervals and for a sufficient period¹. Bad prescription pattern often leads to ineffective and unsafe treatment, increasing the medication cost, increases the chance of adverse consequences and drug interactions and finally causes distress and harmful to the patients⁴.

Gender difference in incidence, presentation, history and outcome for common liver disease. These differences are important for the clinician to recognise and diagnose for the patient and the potential for progressions of liver disease⁸. Diagnosis was based on taking the history of patient, liver function tests and ultrasonography. Management of the patient was completely based upon clinical manifestation and severity of disease¹⁵. According to NLEM, Hepamerz and Ursodiol are the most commonly prescribed liver protectives, followed by Liveril which is excluded from NLEM but widely prescribed⁴. Identification of prescription pattern enabled us to determine the most used drug in hepatic dysfunction and drug dosage adjustment, which helps to identify the better treatment regimen for treatment. The purpose of study was to identify the clinical profile and prescription pattern associated with liver dysfunction and thus to decrease the circumstances of becoming a liver dysfunction patient and to minimize the risk to develop complications. The objectives include demographic analysis to probe the age group and gender, more prone to liver disease.

II. Materials and Methods

Case files of the patients who were admitted for the treatment of hepatic dysfunctions in the department of general medicine at VIMS, Ballari, were used for the study. It was a prospective observational study, ethical clearance was obtained by the concerned committee and informed consent was obtained from each patient. The study was carried out in department of general medicine VIMS, Ballari for a period of 6months and totally 160 patients were studied.

The inpatients of age 18-65years both male and female who were diagnosed with liver disease were considered for the study. The patients under the age of 18 and above 65, outpatients, patients of special departments like psychiatry, OBG and those who were not willing to sign informed consent form were excluded from the study. The information was analysed from the case files, interaction with patients and was represented in the form of tables and diagrams in excel format, then the data was summarized using standard mean method and the report was prepared.

III. Result

A prospective observational study was conducted from October 2018 to March 2019 among the inpatients of Vijayanagara Institute of Medical Sciences, Ballari, Karnataka. In 160 patients, occurrence of hepatic dysfunctions was more in the age group of 30-49 years (n=85), which was same for males (n=79) whereas in females it was more common in age group of 50-65 years (n=16) (Shown in **Figure-01**). Out of total cases, 123(76.88%) patients were found to be alcoholic and 37(23.13%) patients were found to be non-alcoholic, in which alcoholic patients were observed to be more (**Figure-02**).

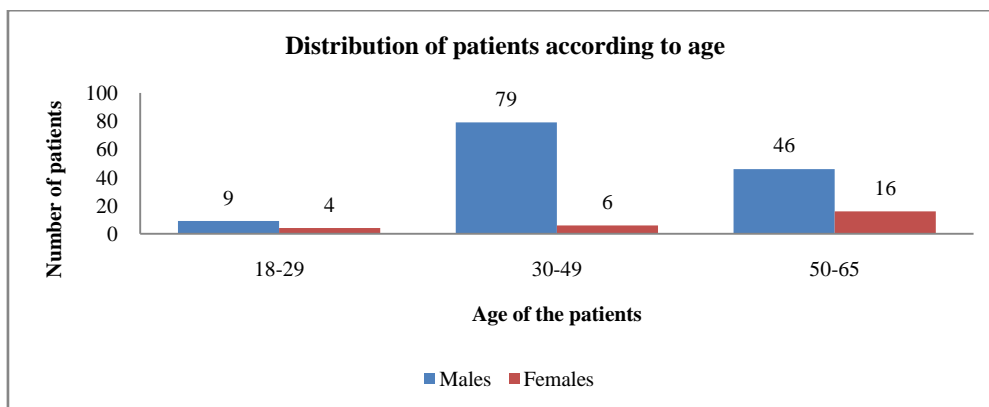


Figure-01:-Distribution of patients according to age.

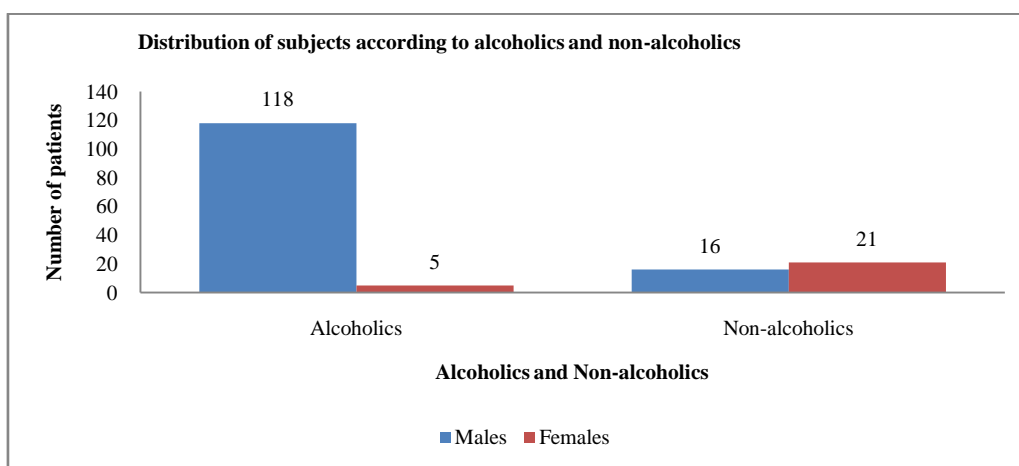


Figure-02:- Distribution of subjects according to alcoholics and non-alcoholics

In comparison for co-morbidities, nearly 140(87.5%) patients were admitted with co-morbidities, in which 122(87.14%) were males and 18(12.86%) were females. Nearly 20(12.5%) patients has been admitted without any co-morbidities, in which 12(60%) were males and 8(40%) were found to be females. The most common co-morbidity was found to be Portal Hypertension which was found to be in 93(66.42%) in which males were found to be 78(83.87%) and females were found to be 15(16.13%) followed by diabetes mellitus(**Figure-03**). The major symptom was found to be Pedal oedema in 91(56.88%) patients, followed by Abdominal Distension in 86(53.75%) patients and breathlessness in 60(37.5%) patients (**Table-01**).

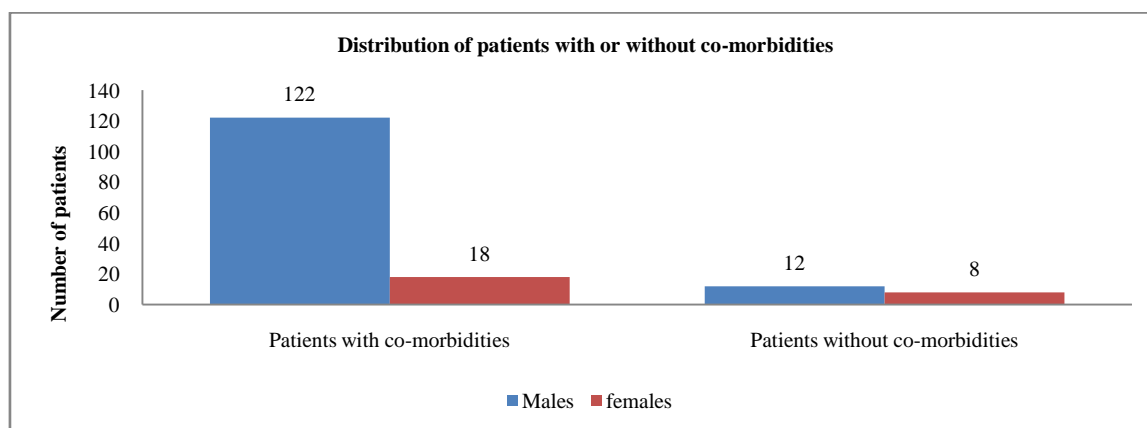


Figure-03:-Distribution of patients with or without co-morbidities

Table 01:Distribution of patients according to the symptoms

S.no	Symptoms	Number of patients	Percentage
01.	Pedal Edema	91	56.88%
02.	Abdominal Distension	86	53.75%

03.	Breathlessness	60	37.5%
04.	Icterus	56	35%
05.	Fever	44	27.5%
06.	Abdominal Pain	36	22.5%
07.	Vomiting	22	13.75%
08.	Decreased urine output	16	10%
09.	Loss of appetite	15	9.38%
10.	Others	87	54.38%

According to WHO Prescribing Indicators, the average number of drugs per encounter among 160 patients was found to be 9.13. The percentage of drug prescribed by generic names was found to be 78.97% (1153 drugs) which was found to be more than the percentage of drugs prescribed by brand names 21.03% (307 drugs). The percentage of drugs prescribed from NLEM was found to be 61.51% (898 drugs) (**Table-02**). The distribution of drugs prescribed for liver diseases are tabulated in **Table- 03**. Among the drugs, Ursodeoxycholic acid has been prescribed to nearly 125(78.13%) patients followed by Pantoprazole in 114(71.25%) prescriptions and syrup Lactulose to 96(60%) patients.

Table-02:Table on prescribing indicators

Sl. No	Indicators	Value
01.	Total number of prescriptions	160
02.	Total number of drugs prescribed	1460
03.	Average number of drugs per prescription	9.13
04.	Percentage of drugs prescribed by generic names	78.97%(1153 drugs)
05.	Percentage of prescriptions with an injection prescribed	100% (160 prescriptions)
06.	Percentage of prescriptions with an antibiotic prescribed	100% (160 prescriptions)
07.	Total number of tablets prescribed	557 (38.15%)
08.	Total number of injections prescribed	678 (46.43%)
09.	Total number of syrups prescribed	114 (7.81%)
10.	Percentage of drugs prescribed from NLEM 2015	61.51% (898 drugs)

Table-03: Distribution of drugs prescribed for Hepatic Dysfunctions

Sl. No	Dosage form	Generic name	NLEM YES/NO	Number of patients	Percentage
01.	Tablet	Ursodeoxycholic acid	NO	125	78.13%
02.	Injection	Pantoprazole	YES	114	71.25%
03.	Syrup	Lactulose	YES	96	60.00%
04.	Injection	Cefotaxime	YES	95	59.38%
05.	Injection	Furosemide	YES	61	38.13%
06.	Tablet	Rifaximine	NO	57	35.63%
07.	Tablet	Propranolol	YES	52	32.5%
08.	Injection	Vitamin-K	NO	51	31.88%
09.	Tablet	Furosemide+ Spironolactone	NO	45	28.13%
10.	Injection	Metronidazole	YES	41	25.63%
11.	Injection	Ondansetron	YES	39	24.38%
12.	Infusion	25% Dextrose	NO	38	23.75%
13.	Infusion	Normal Saline	NO	35	21.88%
14.	Tablet	Spironolactone	YES	33	20.63%
15.	Injection	Noradrenalline	YES	31	19.38%
16.	Injection	Ceftriaxone	YES	30	18.75%
17.	Tablet	Paracetamol	YES	24	15%
18.	Injection	Vitamin-B1	NO	24	15%
19.	Suppository	Looz Enema	YES	24	15%
20.	Infusion	Dextrose Normal Saline	NO	23	14.38%

Drug combinations have been prescribed frequently. But the combinations have been prescribed by their brand names. Nearly 79 (49.38%) drug combinations were prescribed. Among them, Lactulose (Furosemide + Spironolactone) has been prescribed in 45 (28.13%) patients followed by PIPZO (Piperacillin +

Tazobactam) has been prescribed in 17(10.63%) prescriptions (**Table-04**). In 160 prescriptions the major class of drugs prescribed were found to be Antibiotics which were found to be 249(17.06%) in number followed by Diuretics which were found to be 150(10.27%) in number (**Figure-04**). In a total of 160 Prescriptions, all the prescriptions were found to be irrational because there was no dose adjustment which was a crucial step for treatment of liver dysfunctions. In irrationalities, the major one was found to be untreated Anaemia in 31(36.04%) prescriptions, followed by breathlessness in 17(20.23%) prescriptions and untreated fever in 8(9.52%) prescriptions.

Table 04: Distribution of prescribed drugs based on their drug combinations

Brand name	Generic drug combination	Number of prescriptions	Percentage
LASILACTONE	Furosemide+ Spironolactone	45	28.13%
PIPZO	Piperacillin +Tazobactam	17	10.63%
AMOXICLAV	Amoxicillin+ Clavulanic Acid	09	5.63%
BUDECORT	Duolin+Budecort Nebulisation	06	3.75%
CEFOBID	Cefoperazone +Sulbactam	01	0.63%
COTRIMOXAZOLE	Trimethoprim + sulfamethoxazole	01	0.63%

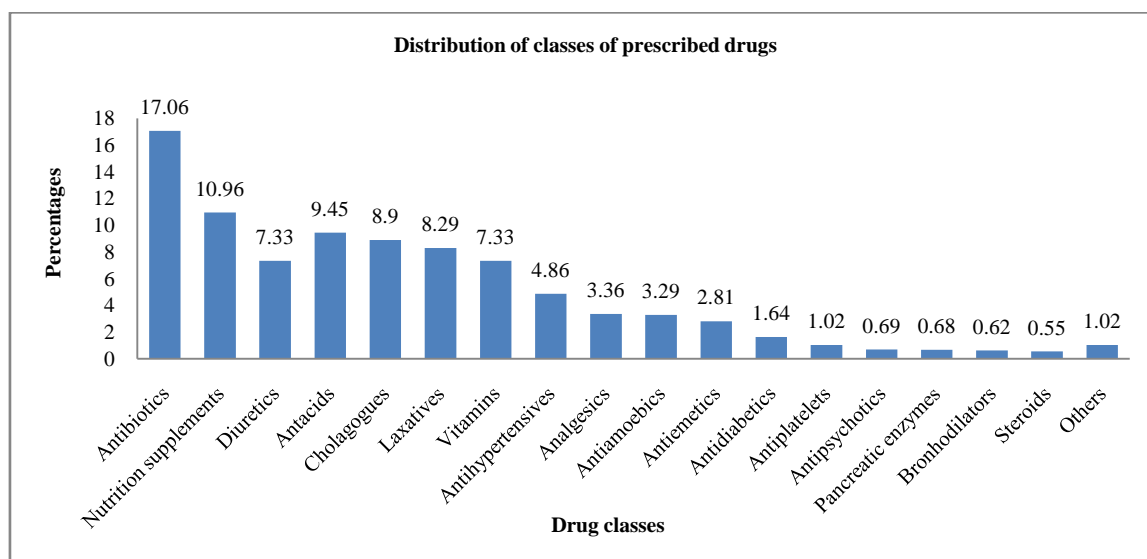


Figure 04: Distribution of prescribed drugs according to their classes

IV. Discussion

A prescription based study was considered to be one of the most effective methods to assess and evaluate drug utilization of medication. It was also important to consider the recommendations by international organisation on Liver diseases that help to improve prescribing practice of physicians and ultimately, the clinical standards. Majority of the population were prone to liver diseases in present trend due to factors like sedentary life style, habits like alcohol, smoking, stress etc.

The study was conducted for a period of 6 months and data was collected in prospective series of inpatients in medicine department who were admitted due to liver dysfunctions. A total of 160 prescriptions were collected in which all basic demographic data of the patient like past medication history, social and family history were gathered. In contrast, a higher number of 1290 prescriptions were analyzed in the study conducted by Anteneh, et al¹⁹. In contrast a total number of 504 prescriptions were analyzed in the study conducted by Gourdas, et al¹⁷. The present prospective study observed that hepatic dysfunctions was more prevalent in males (139) than in females (26). Instead, the above trend can be attributed to the sedentary lifestyle, drinking alcohol beyond the limits. In correlation, a study conducted by Bhanu Prakash, et al⁶ showed that prevalence in males 98%) is more than their females (2%).

The study included the subjects who were aged more than 18 years and the majority of the patients were in the age group of 30-49 in males and 50-65 years in females. This was strongly in liasion with the study conducted by Bhanu Prakash, et al⁶. where the majority of the patients were in the age group of 41-50 years in males and 51-60 years in females. Even though, many studies indicate that women develop liver diseases by consuming lower amount of alcohol and for shorter period of time when compared to men. In our study, only 26 out of 160 patients who were included in the study were females. This may be due to socio-cultural aspects of this country, where almost exclusively males were involved in alcohol intake. Co-morbidity means the patient was simultaneously suffering from a number of diseases, 140(87.5%) cases as co-morbid, rest all cases observed

as a morbid or single disease. The most common co-morbidity was found to be CLD with Portal Hypertension which was found to be in 93(66.42%). This was in correlation with the study conducted by Satish Kumar, et al.¹⁸ which was found to be 89(59.3%) are with co-morbidities and rest(40.66%) were with morbidities. In our study, the total number of drugs prescribed for 160 patients were 1460 drugs, the average number of drugs per prescription was 9.13 which are found to be higher than standard WHO prescribing indicators (1.6-1.8). Percentage of drugs prescribed by generic names was 78.97%, which was found to be much lesser than the standard (100%). The percentage of prescriptions with an injection prescribed was found to be 100% which was much higher than the standard (13.4-24.1%). This may possibly due to confidence of physicians as injections shows faster onset of action than the oral drugs. The percentage of drugs prescribed from NLEM were found to be 61.51% which shows that the drugs were prescribed irrationally. These findings are similar to Zeibshah, et al¹ and contrast to Vinayak, et al⁵. Nearly 79(49.38%) drug combinations were prescribed which was found to be lesser than the drug combinations prescribed in a study conducted by Vinayak, et al⁵ which was found to be 84. The major class of drugs prescribed were found to be Antibiotics (17.06%), followed by nutrition supplements (10.96%) which were found to be in contrast with the study conducted by Zeebaish, et al¹ in which diuretics were found to be major followed by antibiotics. Some of the drugs which were eliminated hepatically need dose adjustments in order to prevent the progression of liver damage, drug toxicity. But in the study of 160 prescriptions of hepatic dysfunctions, no dose adjustment has been found for the drugs like metoprolol, chlorthalidone, diazepam, cefotaxime etc. This may lead to worsening of the liver functions. We found that various risk factors among total 160 patients such as alcoholism, smoking, OTC medications, poor quality of life, infections, stress. Alcohol intake, smoking and poor quality of life were the highest risk factors for the hepatic dysfunctions in males. OTC medications, poor quality of life were the highest risk factors for liver diseases in females.

V. Conclusion

In this uni-centred study, we found that the predominant cause of liver disease was alcohol intake, and males were more prone to liver disease because of alcohol, cigarette smoking, sedentary life style. The males of age 30-49 are mostly affected by liver disease, whereas females of age 50-65. Chronic Liver Disease with Portal Hypertension was the most frequently occurring co-morbidity and pedal edema is the intense symptom seen. In a total of 1460 drugs prescribed, Ursodeoxycholic acid was on the top of the list. Also, Lactulose (Furosemide+Spironolactone) was on the top of combinations. While considering the rationality of the prescriptions, a failure in tapering of dose was observed in every prescription. Ursodeoxycholic acid was the only liver protectant prescribed, which was not mentioned in NLEM-2015. According to NLEM, the most widely prescribed drugs in our hospital were pantoprazole, lactulose, cefotaxime, furosemide, rifaximin etc.

According to WHO standard prescription guidelines the values for average number of drugs per prescription, generic drugs, injections from prescribing indicators and drugs from NLEM shows deviation. Hence more multi-centred studies were required to be conducted to draw the best results on prescription pattern of liver diseases in India. In order to ensure proper prescription habits these factors should be monitored closely in Indian hospitals. The major therapeutic goal in patients with severe alcoholism is self-denial from alcohol which reduces the risk. Increasing the involvement of clinical pharmacist in clinical rounds by promoting rational drug use and drug adherence may improve the quality of health care.

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